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IN THE UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE SELENIOUS ACID LITIGATION	C.A. No. 2:24-cv-07791 (BRM) (CLW) (Consolidated)

PLAINTIFF'S ANSWER TO DEFENDANT ASPIRO PHARMA LTD.'S ANSWER AND COUNTERCLAIMS

Plaintiff/Counterclaim Defendant American Regent, Inc. ("ARI"), by its undersigned attorneys, hereby responds to the Answer, Affirmative Defenses, and Counterclaims of Defendant/Counterclaimant Aspiro Pharma Ltd. ("Aspiro") (ECF No. 65; hereinafter, the "Counterclaims") as follows:

GENERAL DENIAL

ARI denies all allegations in Aspiro's Counterclaims except for those specifically admitted below. With respect to the allegations made in the Counterclaims, upon knowledge with respect to ARI's own acts, and upon information and belief as to other matters, ARI responds and alleges

as follows:

THE PARTIES

1. Aspiro is a corporation organized and existing under the laws of India with its principal place of business at House No. 8-3-166/7/1, 3rd Floor, Erragadda Hyderabad, Telangana, 500018 India.

ANSWER: On the basis of Aspiro's Answer to Paragraph 3 in the Counterclaims, ARI admits that Aspiro is a corporation organized and existing under the laws of India. ARI lacks information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 1, and therefore denies them.

2. On information and belief, ARI is a corporation organized and existing under the laws of the State of New York, with a principal place of business at 5 Ramsey Road, Shirley, New York 11967.

ANSWER: Admitted.

JURISDICTION AND VENUE

3. This Court has subject matter jurisdiction over these Counterclaims for declaratory judgment pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202; based on an actual controversy between Aspiro, on the one hand, and ARI on the other hand, arising under the Patent Laws of the United States, 35 U.S.C. §§ 1 *et seq*.

ANSWER: Paragraph 3 states legal conclusions for which no response is required. To the extent a response is required, ARI admits that Aspiro purports to bring these Counterclaims under the patent laws of the United States and 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202. ARI does not contest subject matter jurisdiction in this judicial district for the purposes of this action only. ARI denies that these Counterclaims have merit or that Aspiro is entitled to any relief on its Counterclaims.

4. This Court has jurisdiction over ARI because, inter alia, ARI subjected itself to the jurisdiction of this Court by filing its Complaint here.

ANSWER: Paragraph 4 states legal conclusions for which no response is required. To the extent a response is required, ARI does not contest personal jurisdiction for purposes of this action only. ARI otherwise denies the allegations of Paragraph 4.

5. Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b).

ANSWER: Paragraph 4 states legal conclusions for which no response is required. To the extent a response is required, ARI does not contest venue in this judicial district for the purposes of this action only. ARI otherwise denies the allegations of Paragraph 4.

FACTUAL BACKGROUND

6. On information and belief, and based on the allegations in the Complaint, ARI is the holder of the New Drug Application ("NDA") No. 209379 for Selenious Acid ((1) eq. 600 mcg Selenium/10 mL (eq. 60 mcg Selenium/mL), (2) eq. 60 mcg Selenium/mL (eq. 60 mcg Selenium/mL), and (3) eq. 12 mcg Selenium/2 mL (eq. 6 mcg Selenium/mL)).

ANSWER: Admitted.

7. On information and belief, and based on the allegations in the Complaint, ARI caused the Food and Drug Administration ("FDA") to list U.S. Patent No. 12,150,957 ("the '957 patent") in the FDA publication, the "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), in connection with NDA No. 209379.

ANSWER: Admitted.

8. The '957 patent lists the title as "Trace Element Compositions, Methods of Making and Use," and the issue date as November 26, 2024.

ANSWER: Admitted.

9. ARI purports and claims to be the owner of, and have the right to enforce, the '957 patent.

ANSWER: Admitted.

10. Aspiro submitted Abbreviated New Drug Application ("ANDA") No. 219633 to the FDA under 21 U.S.C. § 355(j) seeking approval to engage in the commercial manufacture, use, importation, offer for sale or sale of Aspiro's proposed drug product containing Selenious Acid ((1) eq. 600 mcg Selenium/10 mL (eq. 60 mcg Selenium/mL), (2) eq. 60 mcg Selenium/mL (eq. 60 mcg Selenium/mL), and (3) eq. 12 mcg Selenium/2 mL (eq. 6 mcg Selenium/mL)) ("Aspiro's ANDA product"). For ANDA No. 219633, Aspiro submitted a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) to the FDA with respect to U.S. Patent No. 11,998,565 ("the '565 patent"),

which is at issue in the related case American Regent, Inc. v. Aspiro Pharma Ltd., C.A. No. 24-7794 (D.N.J.) (the "Related Action").

ANSWER: ARI admits that, by letter dated June 11, 2024, (the "Aspiro Notice Letter"), Aspiro notified ARI that Aspiro submitted ANDA No. 219633 to market generic versions of selenious acid solutions, intravenous, 600 mcg Selenium/10 mL (eq. 60 mcg Selenium/mL) and 12 mcg Selenium/2 mL (eq. 6 mcg Selenium/mL). ARI otherwise denies the allegations in Paragraph 10.

11. Aspiro sent notice of the certification with respect to the '565 patent to ARI on or about June 11, 2024 (the "Notice Letter"). On information and belief, and as ARI alleges in its Complaint, ARI received the Notice Letter.

ANSWER: ARI admits that the Aspiro Notice Letter notified ARI that Aspiro submitted ANDA No. 219633 to market a generic version of Selenious Acid Injection USP prior to the expiration of the '565 patent. ARI further admits that the Aspiro Notice Letter contained arguments and/or positions that the '565 patent is invalid and/or not infringed, which are not grounded in fact or law and raise material issues to be resolved in later stages in this proceeding, including claim construction issues and patent infringement and validity issues that will be the subject of fact and expert discovery, neither of which have occurred. ARI denies that Aspiro's factual and legal bases have merit. ARI otherwise denies the allegations in Paragraph 11.

12. On December 13, 2024, ARI filed suit in this Judicial District against Aspiro in connection with ANDA No. 219633 alleging infringement of the '957 patent.

ANSWER: Admitted.

13. In view of the foregoing, there has been, and is now, an actual, substantial, and continuing, justiciable controversy between Aspiro and ARI having sufficient immediacy and reality to warrant the issuance of a declaration of rights by the Court with respect to noninfringement and/or invalidity of the '957 patent, and as to Aspiro's right to obtain FDA approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of Aspiro's ANDA product.

ANSWER: Paragraph 13 states legal conclusions for which no response is required. To the extent a response is required, ARI admits there is a present, genuine, and justiciable controversy that exists between ARI and Aspiro regarding Aspiro's infringement of the '957 patent. ARI specifically denies that there is a present, genuine, and justiciable controversy regarding invalidity of the '957 patent.

COUNT I
DECLARATORY JUDGMENT OF NONINFRINGEMENT OF U.S. PATENT NO. 12,150,957

14. Aspiro incorporates by reference and re-alleges each of the foregoing paragraphs of Aspiro's Answer and Affirmative Defenses to the Complaint and these Counterclaims as if fully set forth herein.

ANSWER: No response is required to the general re-allegation and incorporation by reference of the foregoing paragraphs of the Counterclaims. To the extent a response is required, ARI incorporates the answers in response to the foregoing paragraphs as if fully set forth herein.

15. Aspiro has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claims of the '957 patent.

ANSWER: Denied.

16. A present, genuine, and justiciable controversy exists between Aspiro, on the one hand, and ARI, on the other hand, regarding, inter alia, the issue of whether the manufacture, use, sale, offer for sale and/or importation of Aspiro's ANDA Product would infringe any valid or enforceable claim of the '957 patent.

ANSWER: Paragraph 16 states legal conclusions for which no response is required. To the extent a response is required, ARI admits there is a present, genuine, and justiciable controversy that exists between ARI and Aspiro regarding Aspiro's infringement of the '957 patent. ARI specifically denies that there is a present, genuine, and justiciable controversy regarding invalidity of the '957 patent.

17. The Court should declare that Aspiro has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claims of the '957 patent.

ANSWER: Denied.

COUNT II
DECLARATORY JUDGMENT OF INVALIDITY OF U.S. PATENT NO. 12,150,957

18. Aspiro incorporates by reference and re-alleges each of the foregoing paragraphs of Aspiro's Answer and Affirmative Defenses to the Complaint and these Counterclaims as if fully set forth herein.

ANSWER: No response is required to the general re-allegation and incorporation by reference of the foregoing paragraphs of the Counterclaims. To the extent a response is required, ARI incorporates the answers in response to the foregoing paragraphs as if fully set forth herein.

19. Upon information and belief, the claims of the '957 patent invalid for failure to comply with one or more of the requirements for patentability of at least 35 U.S.C. §§ 101, 102, 103, 112, and/or 251 *et seq.*, and/or are invalid under the doctrine of obviousness-type double patenting and/or for any other judicially created and/or non-statutory basis for invalidity or unenforceability.

ANSWER: Denied.

20. There is a real, substantial, and justiciable controversy between Aspiro and ARI concerning whether the claims of the '957 patent are invalid and/or unenforceable for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, 251, and/or pursuant to common law and/or equitable doctrines.

ANSWER: Paragraph 20 states legal conclusions for which no response is required. To the extent a response is required, ARI admits there is a present, genuine, and justiciable controversy that exists between ARI and Aspiro regarding Aspiro's infringement of the '957 patent. ARI specifically denies that there is a present, genuine, and justiciable controversy regarding invalidity of the '957 patent.

21. The Court should declare that the claims of the '957 patent are invalid and/or unenforceable.

ANSWER: Denied.

PRAYER FOR RELIEF

ARI denies that Aspiro is entitled to any judgment or relief against ARI and, therefore specifically denies Paragraphs (A)–(F) of Counterclaimant Aspiro's Prayer for Relief.

Each averment and/or allegation contained in Aspiro's Counterclaims that is not specifically admitted herein is hereby denied.

ARI requests that judgment be entered in its favor, dismissing Aspiro's Counterclaims with prejudice, awarding ARI's attorneys' fees and costs incurred in this litigation under 35 U.S.C. § 285, and granting even further relief as the Court may deem just and proper.

Dated: January 28, 2025

By: s/ Charles H. Chevalier

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CERTIFICATE OF SERVICE

I hereby certify that on January 28, 2025, a true and correct copy of Plaintiff's Answer to Defendant Aspiro Pharma Ltd.'s Answer and Counterclaims was served by ECF on all counsel of record and electronic mail on all counsel of record for Aspiro.

Date: January 28, 2025

s/ Charles H. Chevalier

Charles H. Chevalier